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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,352	07/20/2005	Karl Okolotowicz	65879-5021	9543

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EXAMINER	
RIDER, LANCE W	

ART UNIT	PAPER NUMBER
4131	

MAIL DATE	DELIVERY MODE
06/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,352	OKOLOTOWICZ, KARL	
	Examiner	Art Unit	
	LANCE RIDER	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1,3-8,10-15 and 17-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 9 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/19/2007 and 04/22/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1, 3-8, 10-15, and 17-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 8th 2009.

Election/Restrictions

Applicant's election with traverse of claims 2, 9, and 16 in the reply filed on June 8th 2009 is acknowledged. The traversal is on the ground(s) that the prior art of Burkett, US Patent 6,086,852 does not break unity by exactly teaching the claimed invention, and therefore does not make the special technical feature a common technical feature, for the following reason.

"Applicant submits that it does not teach that peak 8 (dye claimed in claim 2) is at least 73% by weight of the total organic dye content of the composition; nor that peak 6 (dye claimed in claim 9) is at least 73% by weight of the total organic dye content of the composition; nor that peaks 6 and 8 are at least 70% by weight of the total organic dye content of the composition, as presently claimed. For example, Fig. 2 in Burkett teaches that peak 6 has an area of 41.88, peak 7 has an area of 112.27, and peak 8 has an area of 270.77. Even if the percentages by weight of each of the peaks were extrapolated from the areas of the peaks in Fig. 2, it would not disclose the compositions of the present invention, i.e., it would not disclose that peak 6 has the

greatest percentage by weight of all peaks, or that peak 8 is specifically at least 73% by weight of the composition as claimed.

This is not found persuasive because the instantly claimed invention does not involve a novel inventive step over the prior art cited. As applicant states, Burkett, US Patent 6,086,852, teaches in columns 15-17, and figure 2, an HPLC purification of the dye composition resulting in a series of peaks. It is therefore clear from this figure alone that the dye compositions were prepared and purified yielding a pure form of the dyes in question, though the collection of the HPLC fractions containing the pure dyes was not specifically disclosed. The inventive step in both the instantly claimed application and the prior art was the production of pure formations of the dyes of peaks 6 and 8. Burkett, US Patent 6,086,852 discloses the formation of these dyes as well as their purification, resulting in the compositions contained in peaks 6 and 8. In these peaks, the dye contents are greater than 73%, or 70% of the total organic dye content. Though Burkett, US Patent 6,086,852,does not disclose the collection of these fractions, it would have been obvious to one of ordinary skill in the art at the time of the invention to use common procedures for the collection of HPLC fractions to obtain the purified dyes disclosed and purified in Burkett, US Patent 6,086,852. As the instantly claimed application shows no novel inventive step over the prior art of Burkett, US Patent 6,086,852 the requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statements (IDS)s, filed by applicant on September 19th 2007 and April 22nd 2009 have been considered by the examiner in the present case.

Priority

This application, filed July 20th 2005 is a national stage entry of PCT/US02/17720 filed on June 4th 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

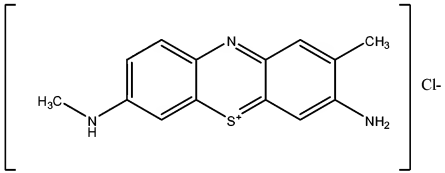
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

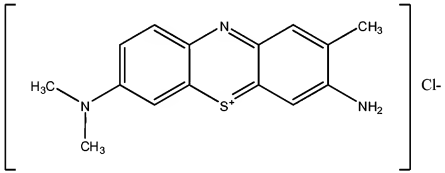
Claims 2, 9, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burkett, US Patent 6,086,852, in view of Cannell, R.J.P., (Natural Products Isolation, 1998).

Claims 2, 9, and 16 are drawn to dye compositions of the following structures alone or in combination.

I.



II.



Burkett, US Patent 6,086,852 discloses in columns 2 and 3, columns 15-17, claims 1-10, and in figures 1 and 2, compositions of dyes having the same structure of

the instantly claimed dyes I and II. Burkett, US Patent 6,086,852 discloses the purification of these dyes by HPLC in figures 1 and 2 yielding individual peaks for each of the dyes, specifically peaks 6 (dye I) and 8 (dye II). The contents of these peaks comprise a mobile phase along with the purified dyes having at least 73% of the total organic dye content being the disclosed dye.

Burkett, US Patent 6,086,852 does not disclose the combination of dyes 6 and 8 only in which they comprise at least 70% of the total organic dye content, or the collection of the peaks as fractions.

Cannell, R.J.P., (Natural Products Isolation, 1998) discloses on pages 199 and 200 methods for collecting fractions of HPLC samples in which, given proper separation, as seen in figures 1 and 2 of Burkett, US Patent 6,086,852, one can arrive at essentially pure samples of HPLC purified compounds. The combination of dyes 6, 7, and 8 could have also been collected as a single fraction from the HPLC run shown in figure 2, depending upon the size of the fractions used. Merely collecting a fraction containing peaks 6-8 would have formed a composition in which dyes I and II would comprise greater than 70% of the total organic dye content. The same result could have also been obtained by collecting fractions containing peaks 6 and 8 separately and mixing them together.

Burkett, US Patent 6,086,852 discloses in column 5, lines 15-35 that purified dyes were required by regulatory requirements at the time, thus it would have been obvious to purify the compounds in such a way as to meet those requirements. It would have been prima facie obvious to one of ordinary skill in the art at the time of the

invention to collect purified HPLC samples, such as those disclosed in Burkett, US Patent 6,086,852, using known methods of fraction collection, such as by pooling a target peak, as disclosed in Cannell, R.J.P., (Natural Products Isolation, 1998). This would allow one to obtain pure compositions of chemical compounds, such as the dyes currently claimed, which would have met regulatory purity requirements.

Conclusion

No claims are currently allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LANCE RIDER whose telephone number is (571)270-1337. The examiner can normally be reached on Monday through Friday, 7:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LANCE RIDER/
Examiner, Art Unit 4131
/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4131